

INTRODUCTION OF THE FAIR BALANCE PRESCRIPTION DRUG ADVERTISEMENT ACT OF 2000

HON. FORTNEY PETE STARK

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Thursday, June 15, 2000

Mr. STARK. Mr. Speaker, I rise today to introduce the Fair Balance Prescription Drug Advertisement Act, a bill to deny tax deductions for unbalanced direct-to-consumer (DTC) pharmaceutical advertising placing more emphasis on product benefits than risks or failing to meet Federal Food, Drug and Cosmetic Act requirements.

This bill will ensure that prescription drug advertisements provide the public with balanced information concerning product risks and benefits. For example, the bill requires that pharmaceutical ads utilize equivalent space and type size in print ads and equal air time in broadcast media—such as television, radio and telephone communication systems—for risks and benefit descriptions. Today, most drug advertising emphasizes product advantages while failing to clearly—if at all—explain often numerous potential disadvantages.

By denying any tax deduction for such advertising, this bill will encourage drug companies to halt these harmful practices that have been shown to increase health care expenditures, mislead the public, adversely affect physician prescribing practices and lead to unnecessary injuries and deaths. Responsibilities of the FDA and Treasury Departments are to be clearly delineated through regulation.

Since the FDA loosened its DTC advertising requirements in 1997, drug companies have doubled their advertising budgets and spent billions extolling the benefits of their products. DTC advertising increased nearly 20-fold during the 1990s. Last year, drug companies spent nearly \$2 billion advertising to consumers, with \$1.1 billion for television ads alone.

As one would expect, such advertising has a direct impact on drug expenditures. DTC advertising leads to more physician office visits, increased patient requests for expensive, brand name drugs—even where a generic drug is available—and over-prescribing of optional “lifestyle” drugs. Americans spent more than \$100 billion on prescription medicines last year—i.e., about 10 cents in every health care dollar. U.S. sales for the antihistamine Claritin, No. 1 in DTC advertising, were \$2.3 billion last year, while the well-advertised heartburn medication, Prilosec, brought-in \$3.8 billion in sales. Not surprisingly, drug spending increased at a rate of about 15%–18% last year and is on the rise.

Contributing to overall increased expenditures, drug prices continue to soar. On average, prices for the 50 most-prescribed drugs for senior citizens increased at twice the rate of inflation over the past six years—with some drug prices increasing at four times the rate of inflation. Business Week reports that the hikes in drug prices are not only tied to new “wonder pills,” but also to the drug industry’s bloated advertising budget.

Such spending is particularly troublesome since consumers receive inadequate informa-

tion about the drugs they purchase. More and more commonly, both television and print ads have become the subject of ridicule due to their inaudible or illegible short list of warnings. A recent cartoon in the Washington Post mocked the typical concluding remarks of a prescription drug TV ad: “WARNING: This drug commercial will be followed by a disclaimer that may cause nausea, disgust, and serious doubts.” A typical Washington Post newspaper ad for Prilosec highlights the drug benefits on a full-page, large print, color ad, and includes a prominent \$10 rebate offer. Yet the most important drug information—warnings, contraindications, indications, usage, precautions and adverse reactions—appear on the next page of the paper, separated by two, full columns of World News and in type size that is almost too small to be read by the naked eye. Unfortunately, such advertising has become the norm.

Although the Federal Food, Drug and Cosmetic Act and the Food and Drug Administration (FDA) regulations and guidelines currently regulate drug advertisements, pharmaceutical ads most often fail to provide the public with adequate information about potentially dangerous drug side effects. RxHealthValue is a new, independent group, representing more than 30 consumer groups, private employers, purchasers, health care providers, labor unions and academics. Last month, this organization recommended that the FDA “develop standards for full disclosure of drug risks and benefits information for all prescription drugs advertised directly to consumers.” The group also called for specifying that “fair balance” means that full disclosure of risks and side effects is given equal print or air time as the description of benefits in the same communication.

I would also like to insert in the RECORD a May 3, 2000 USA Today article providing further evidence of the need for adequate information about drug risks. According to the article, less than 1% of physicians have seen a drug label in the last year. And “in many cases, patients never even see the package insert, and when they do, the tiny typeface and medical jargon often leave them more confused than ever.” These inserts are jam-packed with important warnings and most often go unnoticed. The article reports that drug labels are complex and fail to provide patients and doctors with critical information. Consequently, many patients and doctors fail to read drug labels, leading to inappropriate prescribing, illness and even death.

The article also cites the recent withdrawals of Rezulin, Posicor, Duract and the anticipated removal of Propulsid as evidence that both patients and physicians are unaware of critical drug information. The FDA noted that after altering Rezulin’s label to recommend monthly liver function tests, less than 10% of patients had the tests. And 85% of the 270 Propulsid-related adverse side-effects reported to the FDA (including 70 deaths) occurred in patients with risk factors already listed on the drug’s label. Similarly, all but one of the 12 cases of adverse events (including four deaths) occurred among patients who took the drug for longer than the recommended ten days.

Adding importance to the need to provide accurate, balanced advertising is the fact that

the news media often misses the facts. According to a study featured in this month’s issue of the New England Journal of Medicine (NEJM), newspaper and television medical reporting is often inadequate or incomplete. The NEJM found that the media often lacks or omits critical information about drug risks, overstates the benefits, cites medical experts without mentioning their affiliation with the drug industry, and fails to provide adequate information about drugs in general. The analysis of 207 recent news stories revealed more than half as completely silent about drug risks or side effects. It is clear both patients and medical professionals need comprehensive drug warning information.

In the event that any drug company claims that changes in tax treatment will directly decrease their investment in research and/or lead to higher drug prices for consumers, I would refer to a recent study that proves how preferential their tax treatment really is today. The nonpartisan Congressional Research Service (CRS) analyzed the tax treatment of the pharmaceutical industry and found taxpayer financed credits contribute powerfully to lowering the average effective tax rate for drug companies—by nearly 40% relative to other major industries between 1990 to 1996.

There should be a responsibility attached to such preferential tax treatment and accurate, balanced advertising on matters affecting people’s lives should be an easy obligation to meet.

The need for this bill is clear. In an environment where the Institute of Medicine (IOM) reported between 48,000 to 98,000 people die every year due to medical errors—with medication errors accounting for one out of 131 outpatient deaths and one out of 854 inpatient deaths—providing medical professionals and consumers balanced information about drug risks and side effects is critical.

By denying tax deductions for unbalanced prescription drug ads, we can change pharmaceutical company behavior to ensure that their advertising includes clear, life-saving information that will better inform the American public, reduce health care expenditures and save lives. I look forward to working with my colleagues to make this a reality.

[From USA Today, May 3, 2000]

COMPLEX DRUG LABELS BURY SAFETY MESSAGE

(By Rita Rubin)

If all the information that’s supposed to be on prescription labels actually were printed there, pill bottles would have to be 2 feet high. At least.

Most people don’t have medicine cabinets the size of refrigerators. So drug labels have evolved into package inserts, those tightly folded sheets of paper covered with fine print detailing risks and benefits. In many cases, patients never even see the package insert, and when they do, the tiny typeface and medical jargon often leave them more confused than ever.

Prescribing and taking medicine has never been more complicated, and critics say patients are becoming sick or dying as a result.

Recent drug withdrawals suggest that doctors, never mind their patients, aren’t keeping up. Either they’re overlooking warnings scattered throughout inserts or they’re not even reading the leaflets.

“Less than 1% of physicians have seen a label in the last year,” cardiologist Robert

Califf, director of Duke University's Clinical Research Center, estimated at a recent Food and Drug Administration advisory committee meeting.

In less than two years, three widely prescribed drugs have been pulled from the market in part, at least, because doctors ignored the package inserts. A fourth will disappear from drugstore shelves this summer for the same reason.

FDA critics say the agency, which regulates package inserts, expects too much of the leaflets. Instead of withholding approval of potentially dangerous drugs, critics say, the agency sends them to market with inserts jam-packed with warnings.

"Should we have relatively dangerous drugs and simply warn people that they might kill or seriously injure them?" asks Thomas Moore, a health policy fellow at George Washington University in Washington, D.C. "My perception is that the top management of the FDA seems to have a more permissive view than we have historically had."

He and like-minded FDA-watchers are quick to tick off Propulsid, Rezulin, Posicor and Duract, four drugs whose inserts underwent multiple revisions as new safety concerns came to light. In each case, the manufacturer also mailed "Dear Doctor" letters to alert physicians of label changes.

Apparently, though, some doctors never saw the warnings, and patients died. The last three drugs are now off the market, and Propulsid, which is used to treat severe heartburn, will follow them by mid-August.

"FDA has an almost ritualistic belief in labeling changes, as if they have some magical property to change behavior," says Jerry Avorn, chief of the division that tracks adverse medication events at the Brigham and Women's Hospital in Boston. "There is very little data to support that belief."

The FDA's own research backs Avorn.

In a "talk paper" in January, the FDA noted that 85% of the 270 Propulsid-related adverse side effects reported to the agency—including 70 deaths—occurred in patients with risk factors already listed on the drug's label, such as congestive heart failure or use of antibiotics or antidepressants.

And after Rezulin's label was changed in late 1997 to recommend monthly liver function tests, the FDA found that far fewer than 10% of patients had the tests.

Apparently, even the agency's expert advisers don't always follow the package insert instructions.

At the recent advisory committee meeting, an FDA staff member had to remind urologists on the panel about how to treat patients with Muse, an injectable impotence treatment. Instead of sending men home with a prescription, doctors are supposed to administer the first dose in their office so they can watch for possible side effects.

FLAWED SYSTEM

In many cases, package inserts "are far from perfect," acknowledges Rachel Behrman of the FDA's medical policy office. "We are working hard to improve that."

Recognizing that patients as well as doctors need to read package inserts, the FDA hopes to make them "more user-friendly, more informative, more consistent," she says.

"If you flip through the PDR, the Physicians Desk Reference, the medication bible that reprints package inserts for nearly all prescription drugs today, some of our labels are very good, and some are not."

The older the drug, the more likely its package insert is to fall in the latter cat-

egory, she says; until recent years, comprehensiveness superceded clarity.

Still, "the best available science is often not communicated adequately to practicing doctors to shape their prescribing decisions," says Avorn, who lectures Harvard Medical School students on the subject.

Rezulin, a diabetes drug, looked so dangerous that Avorn and his colleagues advised diabetes doctors at their hospital to stop prescribing it a year before Parke-Davis, at the FDA's urging, pulled it from the market. "I'm astonished that the additional year of product life even existed," Avorn says.

Why does the FDA approve such medications and allow them to stay on the market? "There are very strong economic and political pressures when a company has spent hundreds of millions of dollars to develop a drug," Avorn says.

Wyeth-Ayerst Laboratories yanked Duract, a painkiller in the same class of drugs as ibuprofen, naproxen and others, from the market in June 1998 after reports of four deaths and eight transplants resulting from severe liver failure. According to the company, all but one of the cases occurred among patients who took the drug for more than 10 days, against the label's advice.

Just two weeks before Duract came off the market, Roche Laboratories pulled Posicor, which is used to treat high blood pressure and chest pain.

Taking Posicor with any of a number of commonly used drugs, including some heart disease treatments, could lead to potentially fatal heartbeat irregularities, the same problem that led to Propulsid's impending withdrawal.

As with Propulsid, changes to Posicor's label were designed to minimize the drug interaction risk.

"In principle, drug interactions can be addressed by appropriate labeling; however, with respect to Posicor, Roche Laboratories believes that the complexity of such prescribing information would make it too difficult to implement," the company wrote in a "Dear Doctor" letter announcing Posicor's withdrawal.

At least one drug, sorivudine for shingles, never made it to the U.S. market because of concerns about the effectiveness of label warnings. The pill was withdrawn in Japan after 15 users died in just its first month on the market. They had developed aplastic anemia, a blood disorder, after taking sorivudine with a common anti-cancer drug.

Three years later, Bristol Myers Squibb representatives argued before an FDA advisory committee that a "black box warning"—like the ones on cigarette packages—would adequately minimize sorivudine's risks.

"No one was convinced that it would work," says Raymond Woosley, chairman of pharmacology at Georgetown University in Washington, D.C., and a member of that committee, which recommended not approving sorivudine.

Because a drug already on the market, acyclovir, provided a similar benefit with far less risk, the agency followed the advisory committee's recommendation, the FDA's Behrman says. "We believed zero deaths was the only acceptable number."

RISK VS. BENEFITS

Rezulin, on the other hand, was the first drug of its class. FDA officials have said the agency sought to remove that drug from the market only after similar, safer medications became available.

"I've heard that line, but I don't buy it," Avorn says. "It's as if we don't have other medications to treat diabetes."

The risk/benefit issue arose at the FDA advisory committee meeting, where panelists recommended approval of Uprima, which would be the second impotence pill on the market.

Pre-market studies showed that the drug can trigger fainting, especially when taken with alcohol, so committee members suggested a black box warning against drinking on Uprima's label.

But panel member Thomas Graboys, who had to leave the meeting early, says he would have voted against Uprima, partly because of concerns about the label's ability to protect patients.

When the condition a drug treats isn't life-threatening, only the lowest level of risk is acceptable says Graboys, director of the Lown Cardiovascular Center at Brigham and Women's Hospital.

Much inappropriate prescribing could be eliminated if doctors actually read package inserts or looked up the drugs in their PDRs before prescribing them, Woosley says.

Instead, they rely on memory, a Herculean task when one considers that one doctor might prescribe scores of drugs. But that's what they're taught to do in medical school, Woosley says. Doctors wrote nearly 3 billion prescriptions last year; the number is expected to reach 4 billion annually by 2004.

"We've got to start by changing the way we teach people," he says. Among his students, "the kid who gets the 'A' is the one who says 'I don't know, but I'll look that up and get back to you.'"

DEPARTMENT OF THE INTERIOR AND RELATED AGENCIES APPROPRIATIONS ACT, 2001

SPEECH OF

HON. CHRIS CANNON

OF UTAH

IN THE HOUSE OF REPRESENTATIVES

Wednesday, June 14, 2000

The House in Committee of the Whole House on the State of the Union had under consideration the bill (H.R. 4578) making appropriations for the Department of the Interior and related agencies for the fiscal year ending September 30, 2001, and for other purposes:

Mr. CANNON. Mr. Chairman, I rise in support of Mr. SUNUNU's Amendment increasing funding for the Payment in Lieu of Taxes program for the FY2001 Interior Appropriations Bill. The government has an unpaid obligation to the towns and counties containing lands owned by the federal government, since these are areas that counties do not own and cannot tax. Without PILT, local governments would be forced to eliminate essential public services that benefit residents and visitors in their respective counties.

The federal government owns large portions of lands in many of the counties that I represent in Utah. For example, 93% of Garfield County is owned by the federal government. Our state uses a vast majority of the PILT reimbursements to support education. For FY2001, Utah plans to spend 49.5% of the state budget on K-12 education, among the highest in the nation. But even with this huge commitment, Utah ranks dead last in per student spending with an average of \$4,008 per year compared to the national average of